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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,139	10/14/2003	Steve Mitchell	KLYC-1075US1	4489

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Sheldon R. Meyer  
FLIESLER DUBB MEYER & LOVEJOY LLP  
Four Embarcadero Center  
Fourth Floor  
San Francisco, CA 94111-4156

EXAMINER

HOFFMAN, MARY C

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

28

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/685,139	MITCHELL, STEVE	
	<b>Examiner</b>	<b>Art Unit</b>	
	Mary Hoffman	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 July 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above claim(s) 70-76 and 78-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-69 and 77 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Specification*

The abstract of the disclosure is objected to because it contains phrases that can be implied and should be avoided, e.g. in an embodiment of the present invention.”

Also, the abstract is not a concise statement of the technical disclosure of the patent application and does not include that which is new in the art to which the invention pertains. Furthermore, the abstract should not include the purported merits of the speculative application of the invention. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

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Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 58-69 and 77 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 58, lines 12-13, applicant positively recites part of a human, i.e. "wherein the contact of the beam on the spinous process of the second vertebrae and the hook secure the base to the first vertebrae". In claim 77, last two lines, applicant positively recites part of a human, i.e. " the spacer on the spinous process of the second vertebrae and the hook secure the body to the first vertebrae". Thus claims 58-69 and 77 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive

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property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite, failing to conform with current U.S. practice. There are grammatical and idiomatic errors, e.g. "vertebrae" is the plural form, when it should be in the singular form of "vertebra". Also, in claim 1, line 8, the limitation "where the base is adapted to be hung on the second vertebrae and while being secured" is unclear, and it appears as though there is a grammatical error in this sentence.

Correction is needed to clarify the meaning of these claims.

Claim 1 recites the limitation "the action" in line 8. There is insufficient antecedent basis for this limitation in the claim.

Claim 77 recites the limitation "the action" in line 11. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 13-26, 30-43 and 47-57, as understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (U.S. Patent No. 5,415,659).

Lee et al. disclose an implant comprising a body/base (FIG. 1, ref. #22), at least one hook/flange extending from the body capable of allowing the body to engage a vertebra (FIG. 1, ref. #30 and #50), a beam extending from the body (FIG. 8, ref. #90), the beam having a distal end that can contact a spinous process of another vertebra, and a device that secures the beam to the body (FIG. 8, ref. #80) and contacts the beam directly (col. 5, lines 35-36) [claim 26]. The beam extends beyond the body and extends beyond the hook (in the vertical direction). The device secures the beam to the body in a plurality of positions (col. 5, lines 31-46). The distal end of the beam, the spacer, is bulbous and is round (FIG. 8, ref. #90). The beam includes an elongated aperture (FIG. 8, ref. # 92). The elongated aperture of the beam receives a post extending from the base (FIG. 8, ref. #80). A lock cooperates with the post of the base to secure the beam to the base (FIG. 1, ref. #82). The device extends through the aperture and can be secured to the aperture in a plurality of positions in order to position the beam relative to the body in a plurality of positions (col. 5, lines 31-46). The body includes a first portion and a second portion (FIG. 2, ref. #32 and #52) with a beam platform located between the first and second portions (FIG. 1, ref. #70). There is a space between the platform and first and second portions. The hook extends from the first portion and another hook extends from the second portion. The device extends

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from the platform. The implant comprises a device that is capable of securing the base to an S1 vertebra (FIG. 2, ref. #72). The spacer (FIG. 8, top end part of ref. #90) has a first end capable of contacting the spinous process of a first vertebra without being attached to the spinous process of the first vertebra, and a beam extending from the first end (FIG. 8, ref. #90). The beam is capable of being mounted to the base, or body, (ref. #22) and the base is capable of being mounted to a second vertebra. The distal end of the beam provides a surface that is at an angle to the beam. The surface is capable of engaging L5 vertebra. The surface that is capable of spreading a contact load between a L5 vertebra and the distal end. The distal end of the beam is capable of engaging a spinous process of a L5 vertebra without being attached to a second vertebra. The distal end of the beam is capable of engaging a spinous process of a L5 vertebra over a conforming contact area. The implant is capable of being positioned between the S1 and L5 vertebra, without being attached to the L5 vertebra. The distal end of the beam includes a convex surface (FIG. 8, ref. #90) that is capable of engaging a spinous process of a L5 vertebra in order to spread the load between the distal end of the beam and the spinous process of the L5 vertebra. No additional hooks extend, or stretch out to a greater length, in a direction opposite the first direction, since hook 24 is stationary and does not extend, while hooks ref. #30 and ref. #50 are the only hooks that can extend [claim 43].

With regard to claims 7 and 8, these claims are being rejected under a second interpretation of the reference. A spacer (ref. #70) is adapted to contact a spinous process wherein the spacer is not attached to the spinous process, a base (ref. #22)

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having at least a flange (ref. #30) adapted to engage a second vertebra, the spacer engaging the base, wherein the spacer extends beyond the base and the flange, and the spacer is in direct contact with the base [claim 7].

With regard to the statements of intended use and other functional statements, e.g. the functional limitations added to claims 1 and 9, they do not impose any structural limitations on the claims distinguishable over Lee et al. which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 10-12, 27-29 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (U.S. Patent No. 5,415,659).

Lee et al. disclose the claimed invention except for the implant being made from a material such as polyetheretherketone, polyaryletheretherketone, and polyetherketoneketone, polyetherketoneetherketoneketone, polyetheretherketoneketone, polyketone, polyetherketone, or titanium. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct at least a part of the device of Lee et al. from a material such as polyetheretherketone, polyaryletheretherketone, polyetherketoneketone, polyetherketoneetherketoneketone, polyetheretherketoneketone, polyketone, polyetherketone, or titanium, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

### ***Response to Arguments***

Applicant's arguments filed 7/26/2006 have been fully considered but they are not persuasive. See underlined portions in the above rejections for segments of the rejections most pertinent to the following comments.

#### ***Claim 1***

In response to Applicant's argument that the Lee et al. patent does not disclose "where the base is adapted to be hung on the second vertebrae and while being

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secured by the action of the first end contacting the first vertebrae”, the examiner respectfully disagrees. First of all, claim 1 has been rejected under 35 U.S.C.112, 2<sup>nd</sup> paragraph, for being indefinite, failing to conform with current U.S. practice because there are grammatical and idiomatic errors and other issues that render the claims unclear, e.g. vertebrae should be vertebra, “the action” lacks antecedent basis, and there is a grammatical error within the phrase “where the base is adapted to be hung on the second vertebrae and while being secured by the action of the first end contacting the first vertebrae” that renders this limitation unclear. As understood, the Lee et al. reference clearly meets the claim limitations of claim 1. The amendment including “where the base is adapted to be hung on the second vertebrae and while being secured by the action of the first end contacting the first vertebrae” is being interpreted as functional language. It is the examiner’s opinion that the device of Lee et al. is capable of being hung on the second vertebra, while at the same time contacting the first vertebra. One need merely hold the device of Lee et al. up to the selected region in the vertebra at an angle contacting the components of the device to the first and second vertebrae, and this functional language is satisfied. The examiner maintains that claim 1 is not sufficient to overcome the Lee et al. reference, since the Lee et al. reference meets the structural limitations and is capable of performing the claimed function.

*Claim 7*

Claim 7 has been rejected using a different, second interpretation of the reference. As discussed in the above rejection, the device of Lee et al. can be considered to meet the limitation “wherein the spacer is in contact with the base” when

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one interprets ref. #70 to be the spacer, ref. # 22 to be the base, and ref. #30 to be the flange.

*Claim 9*

The phrase “wherein the device relies on pressure exerted by the L5 vertebrae on the distal end of the beam to secure the device to the body” is also being considered as functional language. This language is met by contacting the distal end of the beam of the device of Lee et al. to the L5 vertebra, and allowing pressure from the L5 vertebra to be exerted on the device. The examiner maintains that claim 9 is not sufficient to overcome the Lee et al. reference, since the Lee et al. reference meets the structural limitations and is capable of performing the claimed function.

*Claim 26*

Applicant asserts that the Lee et al. reference does not disclose “the device contacts the beam directly” as required in claim 26. The examiner respectfully disagrees with Applicant, since it is clear in column 5, lines 35-36 that ref. #83 (the device) contacts the beam directly (by cooperating with slots ref. # 92 to prevent rotation of the beam). Therefore, it is the examiner’s opinion that the Lee et al. device does disclose “the device contacts the beam directly”.

*Claim 43*

The device of Lee et al. can be considered to have two extendable flanges/hooks (ref. #30 and ref. #50) and one stationary flange/hook (ref. #24). Therefore, the device of Lee et al. can be considered to meet the current limitations of claim 43, i.e. wherein no additional hooks extend in a direction opposite the first direction, since hook 24 is

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stationary and does not extend, while hooks ref. #30 and ref. #50 extend, meaning to extend or stretch out in length, in a first direction along the mid-sagittal plane by using grooves ref. #56, shown in FIG. 2. Also see column three, last paragraph.

*Claims 58 and 77*

These claims and the dependents thereof are being rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter, i.e. they claim a part of the human body. Applicant positively recites part of a human, i.e. "wherein the contact of the beam on the spinous process of the second vertebrae and the hook secure the base to the first vertebrae" and "the spacer on the spinous process of the second vertebrae and the hook secure the body to the first vertebrae". The suggested change is "...configured to secure the base to the first vertebrae ..." and "...configured to secure the body to the first vertebrae ...". It is further noted that even if these phrases could be interpreted as functional statements rather than being rejected under 35 U.S.C. 101, these limitations would not be sufficient to overcome the prior art, since the prior art is capable of performing the function of being "...configured to secure the base to the first vertebrae" and "...configured to secure the body to the first vertebrae".

*35 U.S.C. 103(a) Rejections*

Regarding applicant's argument for the withdraw of the 103(a) rejections since they depend from the amended claims 1, 7, 9, 26, 43, and 58, the Examiner asserts that the rejections are still proper because the amended claims 9, 26, 43, and 58 are still rejected as explained above.

Therefore, the rejections are deemed proper.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

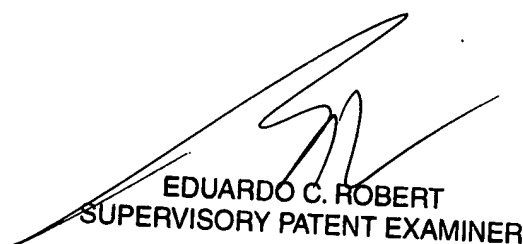
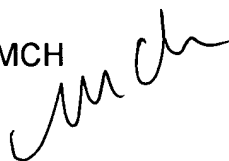
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH



EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER